

## **AMENDMENTS TO THE CLAIMS**

The following listing of claims will replace all prior versions and listings of claims in the application.

### **LISTING OF CLAIMS**

1. (Original) An image guided navigation system for guiding an instrument through a region of a patient, said image guided navigation system comprising:

an anatomical gating device operable to sense a physiological event;

an imaging device operable to capture image data of the region of the patient in response to said physiological event;

a tracking device operable to track the position of the instrument in the region of the patient;

a controller in communication with said anatomical gating device, said imaging device and said tracking device and operable to register said image data with the region of the patient in response to said physiological event, said controller further operable to superimpose an icon representing the instrument onto the image data of the region of the patient, based upon the position tracked by said tracking device; and

a display operable to display the image data of the region of the patient with the superimposed icon of the instrument.

2. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is operable to synchronize image data in the region of the patient in response to said physiological event by capturing an image in response to said physiological event.

3. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is operable to synchronize image data in the region of the patient in response to said physiological event by sampling image data from an acquired image in response to said physiological event.

4. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is selected from a group of 2D, 3D or 4D imaging devices comprising a C-arm fluoroscopic imager, a magnetic resonance imager (MRI), a computed tomography (CT) imager, a positron emission tomography (PET) imager, an isocentric fluoroscopy imager, a bi-plane fluoroscopy imager, an ultrasound imager, a multi-slice computed tomography (MSCT) imager, a high-frequency ultrasound (HIFU) imager, an optical coherence tomography (OCT) imager, an intra-vascular ultrasound imager (IVUS), an ultrasound imager, an intra-operative CT imager, an intra-operative MRI imager, a single photon emission computer tomography (SPECT) imager, and a combination thereof.

5. (Original) The image guided navigation system as defined in Claim 1 wherein said tracking device is selected from a group comprising an electromagnetic tracking device, an optical tracking device, a conductive tracking device, a fiberoptic tracking device, and a combination thereof.

6. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is a C-arm fluoroscopic x-ray imaging device operable to generate multiple two-dimensional images of the region of the patient.

7. (Original) The image guided navigation system as defined in Claim 1 wherein said tracking device is an electromagnetic tracking device having a transmitter coil array operable to generate an electromagnetic field in the region of the patient and a plurality of sensors associated with the instrument operable to sense the electromagnetic field.

8. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument is operable to deliver a therapy to the patient.

9. (Original) The image guided navigation system as defined in Claim 8 wherein the therapy is selected from a group comprising lead placement, drug delivery, gene delivery, cell delivery, ablation, and a combination thereof.

10. (Original) The image guided navigation system as defined in Claim 1 wherein said controller is further operable to provide an estimated optimized site to navigate the instrument to.

11. (Original) The image guided navigation system as defined in Claim 1 wherein said controller is further operable to register said image data with the region of the patient using a registration technique selected from at least one of point registration, surface registration, path registration, 2D to 3D registration 3D to 3D registration and 4D to 4D registration.

12. (Original) The image guided navigation system as defined in Claim 1 wherein the position of the instrument is detected at said physiological event and said imaging device captures the image data at said physiological event, such that the position of the instrument is synched with the captured image data.

13. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument is selected from a group comprising a catheter, a guide wire, a stylet, an insert, a needle and a combination thereof.

14. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument includes at least one sensor selected from a group comprising electrical sensor, a pressure sensor, electro physiological (EP) sensor, a hemo-dynamic sensor, an impedance sensor, and a temperature sensor.

15. (Original) The image guided navigation system as defined in Claim 14 wherein said signal from one of said sensors is utilized to provide an estimated optimized site to navigate the instrument to.

16. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument is a guided biopsy catheter operable to be tracked by said tracking device through the region of the patient.

17. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument delivers a therapy in response to said sensed physiological event from said anatomic gating device.

18. (Original) The image guided navigation system as defined in Claim 17 wherein said therapy is selected from a group comprising drug delivery, gene delivery, cell delivery, ablation, lead delivery, stent delivery, implant delivery, and a combination thereof.

19. (Original) The image guided navigation system as defined in Claim 17 wherein said gated delivery includes simultaneous stimulation of the therapy.

20. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument is guided through a cerebrospinal fluid tree or vascular tree of the patient.

21. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is an ultrasound imaging device located outside of the patient, wherein the image data generates a virtual view from the instrument.

22. (Original) An image guided navigation system for navigating to an optimized site in the patient using image data, said image guided navigation system comprising:

an instrument operable to be navigated to the optimized site;

a tracking device attached to said instrument and operable to be used to track the position of the instrument in the patient;

at least one sensor attached to said instrument and operable to sense a physiological parameter in the patient;

a controller operable to track the position of the instrument with said tracking device and operable to receive the sensed physiological parameter from said sensor, said controller further operable to estimate the optimized site and superimpose an icon representing the location of the optimized site and an icon representing the instrument, based on the sensed physiological parameter and on the position of the instrument; and

a display operable to display the icon of the estimated optimized site and the icon representing the instrument in the patient.

23. (Original) The image guided navigation system as defined in Claim 22 wherein said instrument is selected from a group comprising a catheter, a guide wire, a stylet, an insert, a needle and a combination thereof.

24. (Original) The image guided navigation system as defined in Claim 23 wherein said tracking device is selected from at least one of an electromagnetic, optical, acoustic, and conductive tracking devices.

25. (Original) The image guided navigation system as defined in Claim 22 wherein said at least one sensor is an ultrasound transducer operable to generate a Doppler effect to provide hemo-dynamic physiological parameters.

26. (Original) The image guided navigation system as defined in Claim 22 wherein said at least one sensor is selected from at least one of a temperature sensor, pressure sensor, hemo-dynamic sensor, EP sensor, impedance sensor, accelerometer, tissue sensor, spectroscopy sensor and a combination thereof.

27. (Original) The image guided navigation system as defined in Claim 22 wherein said controller is further operable to generate an atlas map based on previously acquired optimized sites.

28. (Original) The image guided navigation system as defined in Claim 27 wherein said atlas map is further utilized to estimate the optimized site.

29. (Original) The image guided navigation system as defined in Claim 22 wherein the optimized site is an optimized lead placement site in a coronary sinus region.

30. (Original) The image guided navigation system as defined in Claim 22 wherein said controller is further operable to register said image data with the patient using a registration technique selected from at least one of point registration, surface registration, path registration, 2D to 3D registration, 3D to 3D registration and 4D to 4D registration.

31. (Original) The image guided navigation system as defined in Claim 22 further comprising an anatomic gating device operable to sense a physiological event wherein said image data is gated to said physiological event and wherein registration by said controller is gated to said physiological event.

32. (Original) The image guided navigation system as defined in Claim 22 wherein said instrument is a guided biopsy catheter.

33. (Original) The image guided navigation system as defined in Claim 22 further comprising a tracking system operable to track said instrument by tracking said tracking device attached to said instrument.

34. (Original) The image guided navigation system as defined in Claim 33 wherein said tracking system is selected from a group comprising an electromagnetic tracking system, an optical tracking device, a conductive tracking system, a fiberoptic tracking system, and a combination thereof.

35. (Withdrawn) An image guided navigation system for navigating a region of a patient, said image guided navigation system comprising:

an imaging device positioned outside the patient and operable to generate image data at the region of the patient;

an instrument operable to be navigated in the region of the patient;

a first tracking device attached to the instrument and operable to be used to track the position of the instrument in the region of the patient;

a controller operable to generate virtual images along the navigated path of the instrument from said image data generated outside the patient; and

a display operable to display the virtual images.

36. (Withdrawn) The image guided navigation system as defined in Claim 35 wherein said imaging device is an ultrasonic probe and said controller is an ultrasonic controller.

37. (Withdrawn) The image guided navigation system as defined in Claim 36 wherein said imaging device is a 3D ultrasonic probe.

38. (Withdrawn) The image guided navigation system as defined in Claim 35 further comprising a second tracking device attached to said imaging device operable to be used to track the position of the imaging device.

39. (Withdrawn) The image guided navigation system as defined in Claim 38 wherein said controller is further operable to automatically register said image data from said imaging device by tracking said imaging device with said second tracking device to said instrument having said first tracking device.

40. (Withdrawn) The image guided navigation system as defined in Claim 35 wherein said virtual images include a plurality of image planes about a distal end of said instrument including a forward image plane.

41. (Withdrawn) The image guided navigation system as defined in Claim 35 wherein said instrument is further operable to deliver a therapy to the patient.

42. (Withdrawn) The image guided navigation system as defined in Claim 41 wherein said therapy is operable to be gated to a physiological event.

43. (Withdrawn) The image guided navigation system as defined in Claim 42 wherein said gated therapy is operable to be dual delivery of both therapy and a stimulus.

44. (Currently Amended) A method for image guiding an instrument in a region of a patient, said method comprising:

identifying a physiological event;

capturing image data duringin response to the physiological event;

registering the captured image data to the patient during the physiological event; and

displaying the location of the instrument on the image data of the region of the patient by superimposing an icon of the instrument on the image data.

45. (Original) The method as defined in Claim 44 further comprising delivering a treatment with the instrument when the instrument reaches a desired location.

46. (Original) The method as defined in Claim 44 further comprising navigating the instrument through the region of the patient.

47. (Original) The method as defined in Claim 44 further comprising sensing a physiological parameter with the instrument.

48. (Original) The method as defined in Claim 47 wherein sensing of the physiological parameter is during the physiological event.

49. (Original) The method as defined in Claim 48 wherein the physiological event is a heartbeat.

50. (Original) The method as defined in Claim 44 further comprising capturing the image data outside the patient with an ultrasound probe and displaying the ultrasound image data from a virtual viewpoint of the instrument.

51. (Original) The method as defined in Claim 44 further comprising delivering a therapy and a stimulus to the therapy.

52. (Currently Amended) A method for image guiding an instrument to an optimized site in a patient, said method comprising:

navigating the instrument in the patient;

detecting a location of the instrument;

sensing a physiological parameter with the instrument;

capturing image data of the patient in response to a physiological event;

automatically determining an optimized site to navigate the instrument to;

and

displaying superimposing an icon of the optimized site and an icon of the location of the catheter on the image data.

53 - 54. (Cancelled)

55. (Original) The method as defined in Claim 52 further comprising delivering a therapy with the instrument at the optimized site.

56. (Original) The method as defined in Claim 55 further comprising delivering the therapy during a physiological event.

57. (Original) The method as defined in Claim 55 further comprising delivering a lead to a coronary sinus region.

58. (Original) The method as defined in Claim 52 wherein the physiological parameter is at least one of a pressure, temperature, hemo-dynamic, acceleration, electrophysiological, and a combination thereof.

59. (Original) The method as defined in Claim 52 further comprising registering the location of the instrument with pre-acquired images using at least one of point registration, surface registration and path registration.

60. (Original) The method as defined in Claim 59 further comprising registering during an identified physiological event.

61. (Original) The method as defined in Claim 60 wherein the physiological event is a portion of the heartbeat.

62. (Original) The method as defined in Claim 52 further comprising delivery a lead through a catheter to the coronary sinus region of the patient.

63. (Currently Amended) An image guided navigation system for guiding an instrument through a region of a patient, said image guided navigation system comprising:

- an anatomical gating device operable to sense a physiological event;
- an imaging device operable to capture image data of the region of the patient in response to the physiological event;
- a tracking device operable to track the position of the instrument in the region of the patient;
- a controller in communication with said anatomical gating device, said imaging device and said tracking device and operable to synchronize captured image data of the region of the patient in response to a physiological event, said controller further operable to register said synchronized image data of the region of the patient in response to said physiological event, said controller further operable to superimpose an icon representing the instrument on to the image data of the region of the patient, based upon the position tracked by said tracking device; and
- a display operable to display the image data of the region of the patient with the superimposed icon of the instrument.

64. (Original) The image guided navigation system as defined in Claim 63 wherein said tracking device is selected from a group comprising an electromagnetic tracking device, an optical tracking device, a conductive tracking device, a fiberoptic tracking device, and a combination thereof.

65. (Original) The image guided navigation system as defined in Claim 63 wherein said controller is further operable to provide an estimated optimized site to navigate the instrument to.

66. (Original) The image guided navigation system as defined in Claim 63 wherein said instrument delivers a therapy in response to said sensed physiological event from said anatomic gating device.